EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: CVMP press release procedure and publication of documents adopted by CVMP		
Applies to: Veterinary Medicines		
Status: **PUBLIC**		Document no.: WIN/V/4001
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1. Changes since last revision

To update the WIN in line with the new format of the CVMP agenda.

2. Records

Electronic copies of the press release document are saved in the appropriately labelled folder in DREAM: *Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/2. Meeting Organisation/MEETINGS/Press Releases/YYYY Press Release*.

Electronic copies of documents mentioned in the press release are saved in relevant product or procedure folder.

3. Instructions

Purpose

The purpose of this WIN is to define the process and responsibilities for developing the CVMP press release; highlighting all steps taken until subsequent publication of the press release and documents adopted by CVMP and distribution of the press release to stakeholders.

Scope

This WIN applies to staff in the Veterinary Medicines Division.

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Responsibilities

It is the responsibility of the Head of Veterinary Medicines to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

Documents needed for this WIN

- CVMP press release template (*Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/2. Meeting Organisation/MEETINGS/Press Releases*)
- Transmission slip for internal approval prior to circulation to CVMP (File\New\Templates\More\Transmission Slips\TS Internal correspondence)
- Transmission slip for publication on external Web (File\New\Templates\More\Transmission Slips\TS General content)
- CVMP MMD agenda (*Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/2. Meeting Organisation/MEETINGS/YYYY/XXXth - Month YYYY*)
- Documents for publication transmission slip and related correspondence templates and guidance (*Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/1. Governance/10. Templates*)

Definitions

Coordinating assistant	Assistant responsible for the coordination of preparation and publication of the press release and summary of opinions or procedural documents to be published after CVMP
CVMP	Committee for Medicinal Products for Veterinary Use
CVMP secretary	PM responsible for CVMP organisation
ECD	Eudra Common Directory
DREAM	Document Records Electronic Archive Management
HDiv	Head of Division
HDep	Head of Department
HSer	Service Head
MA	marketing authorisation
MRLs	Maximum residue limits
PM	Project manager
PSUR	Periodic safety update report
TS	Transmission slip
VICH	Veterinary international cooperation and harmonisation

Instructions

Step	Action	Responsibility
1.0	**Preparation of CVMP press release (prior to CVMP meeting)**	
1.1	Prepare 1st draft of press release prior to meeting on the basis of the agenda circulated to the CVMP with the 2nd mailing (1 week prior to the CVMP meeting), by putting each item that is under the following points on the CVMP agenda, including the ones in Annex I, on the draft press release, using the corresponding press release model text from the template: • section 1.1 and 1.4, CVMP opinions for MRL *for adoption* • section 2.1 and 2.4, CVMP opinions for MAs *for adoption* • section 4, Referral procedures: start of procedures and CVMP opinions *for adoption* • section 5.2, Annual reassessments: CVMP opinions *for adoption* • section 5.4, Renewals of MA:CVMP opinions *for adoption* • section 5.5, PSUR: assessment reports *for adoption* • section 6.1 VICH guidelines *for adoption* • section 7.1, scientific advice reports *for adoption* • sections 7.2-7.11 as applicable, working parties: work plans, mandates, guidelines, concept papers, reflection papers and Questions and Answers (Q&A) documents *for adoption* • section 8.1, Other MRLs items: list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 ("out of scope list") *for endorsement* • section 9, Availability of medicines: items *for decision* • Other points as needed (for example: Chair/Vice-chair elections announcements, other meetings of interest, important procedural announcements, etc.) Send link to the press release from DREAM to CVMP secretary for review.	Coordinating Assistant
1.2	Check and modify the 1st draft of the press release, as needed.	CVMP secretary
1.3	Circulate to all PMs in the division/department by Wednesday prior to the CVMP meeting week for checking and completion of text. Send a reminder on Friday prior to the CVMP meeting to PMs for updating of the draft press release and to nominated staff[1] in the Press Office of the Communications department for information.	Coordinating Assistant

[1] For names, check with Press Office

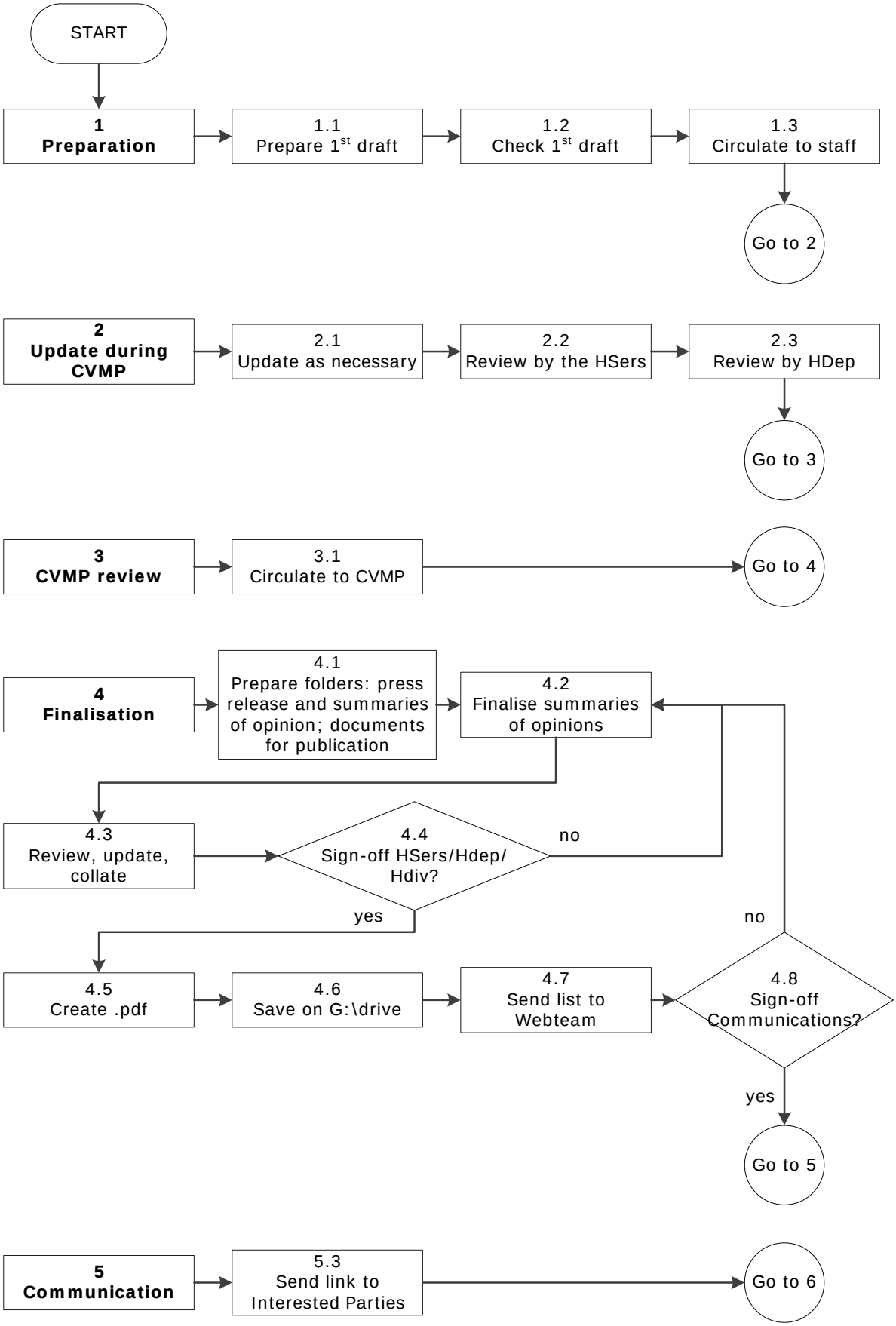
2.0		**Update of CVMP press release (during the CVMP meeting)**	
	2.1	Update press release during the meeting in accordance with the decisions taken and comments received, if applicable, by 15.00 on the 2nd day of the CVMP meeting (normally Wednesday).	PMs
	2.2	On 2nd day of the CVMP meeting (normally Wednesday) after 15:00 send an email with the link from DREAM to all HSer for review and comments by end of business on the same day.	Coordinating Assistant
	2.3	On the 2nd day of the CVMP meeting (normally Wednesday) following the review by HSer, prepare and circulate a folder with paper copy and TS for internal correspondence to HDep.	Coordinating Assistant
3.0		**CVMP review**	
	3.1	No later than 13:00 on last day of the CVMP meeting (normally Thursday) circulate the agreed draft press release to CVMP members via Eudralink for their comments within 24 hours.	Coordinating Assistant
4.0		**Finalisation and publication of the CVMP Press Release and Summary of Opinions**	
	4.1	Before 14:00 on the same working day as end of the CVMP meeting (usually Thursday), prepare separate sign off-folders and transmission slips for the press release and summary of opinions (using the TS for general content) for publication at the same time. On the same day, prepare and save in DREAM the TS for the documents for publication after CVMP, i.e. concept papers, guidelines and any other document pending publication following the CVMP meeting, (see CVMP Month YYYY - Documents for publication - TS (template) in *Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/1. Governance/10. Templates*) and place an empty sign-off folder on Coordinating Assistant's desk to collect them. Send an email to PMs and Assistants informing that the TS for documents for publication is available for completion (see e-mail template and attachments in *Cabinets/02b. Administration of Scientific Meeting/CVMP - Administration/1. Governance/10. Templates/E-mails templates*) and that the deadline for putting documents in the folder is Monday after CVMP, end of business.	Coordinating Assistant
	4.2	Finalise summary opinions of MAs, MRLs and List of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (if applicable) and submit via email for collation to Coordinating Assistant.	PMs; Assistants
	4.3	Review comments received and update press release, as needed (consulting CVMP secretary, if necessary). Collate summary opinions (if applicable).	Coordinating Assistant

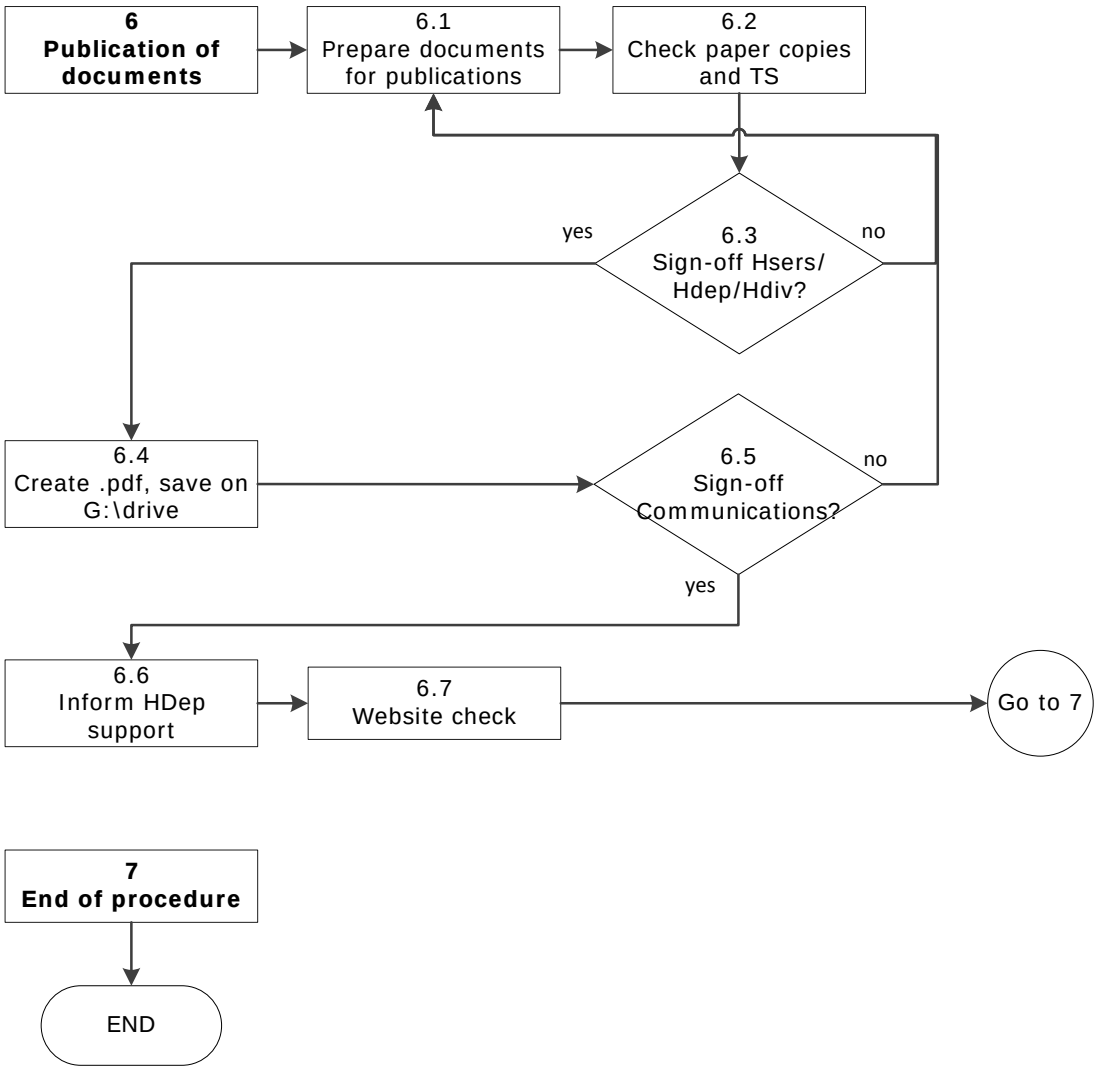
4.4	By 14:00 on same working day as end of the CVMP meeting (normally Thursday), submit the press release and summary of opinions folders (as applicable) to CVMP secretary, HSer, HDep and HDiv for approval. Has the package been approved, and no further comments were received? If no, send comments to Assistants/PMs as applicable and go to 4.2. If yes, request Assistants to finalise documents as applicable and go to 4.5.	Coordinating Assistant
4.5	Create .pdf versions of summary of opinions, as applicable. Use either the DREAM rendition functionality or Adobe. Open the document and change the properties of the summary of opinions to have the following description: Author: CVMP Title: <Product name> summary of opinion Subject: Summary of opinion Keywords: <Product name>, summary of opinion Send .pdf version of document to Coordinating Assistant.	Assistant
4.6	Create .pdf version of press release. Use either the DREAM rendition functionality or Adobe. Save electronic versions of received summary of opinions and of press release (press release also as word version) in the sign-off folder (G:\External Information Draft\SIGN OFF\Veterinary Unit\CVMP). Open the press release and change the properties to have the following description: Author: CVMP Title: CVMP press release Subject: Press release Keywords: CVMP press release	Coordinating Assistant
4.7	Send via email a list of documents to publish for information to the Webteam of the Communications department.	Coordinating Assistant
4.8	Submit approved press release and summary of opinions to the Press office of the Communications department for sign-off on working day following end of the CVMP meeting (normally Friday) by 14:00. Has the Communications department approved the document package? If no, go to 4.2 If yes, go to 5.0	Coordinating Assistant

5.0		**Information to interested parties**	
	5.1	Normally on Monday after CVMP - once the press release is published on the Agency's website - send a link to the published page via email to Interested Parties (ECD group: "Press – Vet Fax (Interested Parties)").	Coordinating Assistant
6.0		**Publication of adopted CVMP documents referred to in the Press Release (except summary of opinions)**	
	6.1	Ensure that concept papers, guidelines and any other document for publication following the CVMP meeting have been finalise, checked and printed for the documents for publication folder and that the TS has been filled with the correct details.	PMs/Assistants
	6.2	On Monday after CVMP around 5 pm check that all documents for publication (concept papers, guidelines and any other document for publication following the CVMP meeting) have been included in the TS and that corresponding paper copies are in the folder (chase missing ones if necessary). Carry out final quality check of the documents and of the entries in the TS.	Coordinating Assistant
	6.3	Start sign-off circulation to CVMP secretary, HSer (only concerned ones), HDep and HDiv for approval. Was the document package approved? If no, inform concerned PMs/assistants and go to 6.1 If yes, go to 6.4	Coordinating Assistant
	6.4	Ask assistants responsible for the documents to create .pdf versions using either the DREAM rendition functionality or Adobe. Open the document and change the properties of the documents as applicable to have the following description: Author: CVMP/European Medicines Agency Title: <Doc Title Agency> Subject: <Document Ref. ID> Keywords: useful keywords or document title Save electronic versions of all documents as .pdf in sign-off folder: G:\External Information Draft\SIGN OFF\Veterinary Unit\CVMP.	Assistants
	6.5	Ensure that all documents have been saved on the G:\drive and submit the folder with paper copies to Communications department for sign off. Has the Communications department approved the document package? If no, inform concerned PMs/assistants and go to 6.1 If yes, go to 6.6	Coordinating Assistant

6.6	Following publication, send the TS (DREAM link) to HDep support to inform about the status of documents, to enable audit of the concerned document process folder in DREAM.	Coordinating Assistant
6.7	Following publication, check that documents are linked properly and published in the correct locations.	Assistants
7.0	**End of procedure**	

Flowchart


START
1 Preparation
1.1 Prepare 1st draft
1.2 Check 1st draft
1.3 Circulate to staff
Go to 2
2 Update during CVMP
2.1 Update as necessary
2.2 Review by the HSers
2.3 Review by HDep
Go to 3
3 CVMP review
3.1 Circulate to CVMP
Go to 4
4 Finalisation
4.1 Prepare folders: press release and summaries of opinion; documents for publication
4.2 Finalise summaries of opinions
4.3 Review, update, collate
4.4 Sign-off HSers/Hdep/ Hdiv?
no
yes
4.5 Create .pdf
4.6 Save on G:\drive
4.7 Send list to Webteam
4.8 Sign-off Communications?
no
yes
Go to 5
5 Communication
5.3 Send link to Interested Parties
Go to 6


6
Publication of documents
6.1
Prepare documents for publications
6.2
Check paper copies and TS
6.3
Sign-off Hsers/ Hdep/Hdiv?
yes
no
6.4
Create .pdf, save on G:\drive
6.5
Sign-off Communications?
no
yes
6.6
Inform HDep support
6.7
Website check
Go to 7
7
End of procedure
END